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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,763	12/27/2005	Patrice Mauriac	270,388	8762

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Jay S Cinamon
Abelman Frayne & Schwab
10th Floor
666 Third Avenue
New York, NY 10017

EXAMINER	
HELM, CARALYNNE E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,763	MAURIAC ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-26 and 28-42* is/are pending in the application.

4a) Of the above claim(s) *30 and 35-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-26, 28-29, and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 15, 2009 has been entered.

Election/Restrictions

To summarize the current election, applicant elected Group I where the active ingredient is only in the core.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for implants having an extended overall release of the active principle that has a portion with a linear profile, does not reasonably provide enablement for implants having an extended overall release of the active principle with a linear profile.

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to implantable medical devices that provide an extended linear profile of drug release. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Kim et al. (Pharmaceutical Research 1995 12:1045-1048) who teach that deviations from linear release profiles in shaped drug delivery devices were known to occur at the time of the invention due to the decrease in surface area of the devices as a result of polymer dissolution (erosion) (see page 1045 column 1 paragraph 1). Coatings were taught to be employed to alleviate this issue, but although they have been demonstrated to improve the issue, they still do not always give a strictly linear release profile (see page 1045 column 1 paragraph 1 and figure 1).

2. The breadth of the claims

The claim breadth and the specification are not commensurate. The specification exemplifies a single geometry of device that has a linear release over a specified period of time, while the claims embrace all device geometries whose release is entirely linear.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for indefinitely achieving a linear release profile as claimed. Applicants' own examples demonstrate that a linear

profile can be obtained initially, but at some point the release profile deviates from linearity (see instant drawings 1B, 3B, 4B, and 5B). At times the deviation is quite dramatic (see instant drawings figure 2B). In addition, when the instant specification discusses linear release profiles that were obtained, it is qualified by a time duration over which they occur (see instant examples 1-3). Applicants did not discuss an indefinite (e.g. until drug is exhausted) linear release duration in the specification and demonstrate a recognition that the time period of linearity is not only finite but dependant on a variety of formulation parameters (drug, coating thickness, device geometry, etc.).

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably made to function as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

5. Suggested alternative language

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Instead of an absolute linear profile, as claimed, the disclosure and the prior art does enable one of ordinary skill to make compositions that generate a release profile in which a portion is linear (e.g. within a finite period, a linear profile can be obtained such as the three weeks, eleven months, etc exemplified in the instant examples).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,620,422 in view of Chou et al. and Jain et al. (see below for citation)

Patent 6,620,422 teach an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary form 1 to 60 μm (see page 3 lines 3-10; instant claims 22-24). The peptide is taught present at 20 to 40% of the implant device. The PLGA has a molecular weight between 50,000 and 150,000 and a lactic acid to glycolic acid ratio of 50:50 to 95:5. An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. Further, PLGA is taught as an envisioned polymer in the core and skin (see paragraphs 10-11). In particular, the outer layer of Chou et al. is taught to minimize burst release by acting (generate linear release profile) as an additional barrier between the drug/polymer matrix and the aqueous outer environment (see paragraph 35).

Jain et al. teach that the proteins exhibit a burst release when contained in a PLGA matrix (see figures 2 and 4).

In light of these additional teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PLGA used in the drug core of the device taught by Maquin et al. in an outer skin as taught by Chou et al. to give additional control of the device release kinetics and reduce any burst that

occurs. Therefore claims 22-25 are obvious over claims 1-3 of U.S. Patent No. 6,620,422 in view of Chou et al. and Jain et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22, 25 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. (previously cited) in view of Wang et al. (previously cited).

Chou et al. teach a co-extruded, implantable drug delivery device composed of a core and outer skin (film) configuration (see paragraph 8). The drug is taught present in the core (see paragraph 9). Further, PLGA is taught as an envisioned polymer in the core and skin (see paragraphs 10-11, 35 and claim 22). In addition, a drug loading level of 40% is taught (see paragraph 35). Based upon these teachings, where PLGA is specifically taught in the core and skin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have PLGA simultaneously in both regions where the drug composed 40% of the core. Chou et al. teach that this PLGA coating gives a linear release profile over several months (see paragraph 65). This reference does not provide particular teachings regarding the molecular weight of the PLGS polymer or the relative proportions of lactic acid and glycolic acid.

Wang et al. teach an implant device comprised of a core and coating where the core contains poly(lactide-co-glycolide) (PLGA) and an active principle dispersed within it, while the coating is the same PLGA used in the core (see page 1059 column 2 paragraph 4-page 1060 column 1 paragraph 2; instant claim 22). Wang et al. also teach that the PLGA used has a 75/25 ratio of lactic acid to glycolic acid and a nominal molecular weight of 100,000 (see page 1059 column 2 paragraph 4; instant claims 25

and 31-32). In addition, Wang et al., teach this configuration as being capable of generating a linear release profile (see figure 2).

Since both Chou et al. and Wang et al. teach polymeric drug cores coated with polymer, where both the core and coating polymer are the same and envisioned as PLGA, it would have been obvious to combine their teachings. It then would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the 100,000 molecular weight 75/25 PLGA taught by Wang et al. as the PLGA in the device of Chou et al. One have ordinary skill in the art would have had a reasonable expectation of success for this combination producing a release profile with a linear region since Wang et al. teach that a partially linear release profile is generated from their particular polymer combination. Applicants have not defined the time duration that corresponds to "extended overall release"; therefore, any duration over which a linear release profile occurs is interpreted to meet this claim limitation. Thus claims 22, 25 and 31-32 are obvious over Chou et al. in view of Wang et al.

Claims 22-23 , 26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. in view of Wang et al. as applied to claims 22, 25 and 31-32 above, and further in view of Jain et al. (European Journal of Pharmaceutics and Biopharmaceutics 2000 50:257-262) and Sakamoto et al. (US Patent No. 4,720,387).

Chou et al. in view of Wang et al. make obvious the composition of claim 22 where the inclusion of an outer coating reduces the burst release of the contained drug

and linearizes the release profile. Chou et al. in view of Wang et al. do not explicitly teach the presence of hydrophilic excipients in the coating film.

Jain et al. teach that the inclusion of a hydrophilic excipient (mannitol) in a PLGA matrix imparts porosity that increases the rate of drug release from the PLGA due to added diffusion (see page 260 column 2 paragraph 1; instant claim 26). The protein myoglobin (peptide) is taught as an envisioned drug that also exhibits a burst release when contained in an uncoated PLGA matrix (see figure 4; instant claim 23). They further teach that increasing the concentration of mannitol increases the release rate. While d-mannitol is not explicitly taught, Sakamoto et al. teach this variety of mannitol as a known hydrophilic excipient in sustained release drug release preparations that increases the rate of drug release when present (see column 10 lines 38-40, table 1 and figure 7; instant claim 29). Thus d-mannitol would have been an obvious selection for the mannitol in Jain et al.

One of ordinary skill in the art would be motivated to modify the release rate of the drug contained in the composition of Chou et al. in view of Wang et al. based upon the teachings of Chou et al. (see paragraph 61). Therefore it would have been obvious to the ordinarily skilled artisan at the time of the invention to include d-mannitol and optimize its concentration as a matter of routine experimentation. It also would have been obvious to utilize a peptide as the drug of choice since it was 1) an exemplified option in Jain et al. and 2) Chou et al. contemplate their "drug" as any agent designed to provide a local or systemic physiological of pharmacological effect when administered to

mammals" (see paragraph 67). Therefore claims 22-23, 26, and 28-29 are obvious over Chou et al. in view of Wang et al., Jain et al., and Sakamoto et al.

Claims 22 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. in view of Wang et al. as applied to claims 22, 25 and 31-32 above, and further in view of Fujioka et al. (US Patent No. 5,851,547).

Chou et al. in view of Wang et al. make obvious the composition of claim 22 where the inclusion of a PLGA outer coating reduces the burst release of the contained drug and linearizes the release profile. Chou et al. in view of Wang et al. do not explicitly teach the thickness of the PLGA coating.

Fujioka et al. teach a controlled release device where a zero order (linear) release profile is desired (see column 3 lines 52-56). The release rate is taught to be controlled by the presence of an outer polymer coating on a drug containing core (see column 5 lines 10-15). PLGA is en envisioned polymer for this outer layer (see column 5 lines 41-42 and 50-53). Fujioka et al. teach that the thickness of the layer is preferably from 100 μm to 1000 μm (see column 8 lines 18-24; instant claims 33-34).

Since Chou et al. in view of Wang et al. and Fujioka et al. utilize PLGA coatings in drug containing polymer cores to generate a linear drug release profile, it would have been obvious to one of ordinary skill in the art to combine their teachings. This ordinarily skilled artisan would then have found it obvious to apply the teachings regarding layer thickness in Fujioka et al. in the invention of Chou et al. in view of Wang et al. and

prepare their device with a 100 μm PLGA coating. Therefore claims 22 and 33-34 are obvious over Chou et al. in view of Wang et al. and Fujioka et al.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maquin et al. (previously cited) in view of Chou et al. and Jain et al.

Maquin et al. teach an extruded subcutaneous implant composed of PLGA and peptide where the peptide is present in particle form whose sizes vary from 1 to 60 μm (see page 3 lines 3-10; instant claims 22-24). The PLGA is taught by Maquin et al. have a molecular weight from 50,000 to 150,000 and a lactic acid to glycolic acid ratio between 50:50 and 95:5 (see page 5 line 32- page 6 line 2; instant claims 22 and 25). In one example, the peptide particles are taught present at 25 wt% (see page 7 lines 11-12; instant claim 22). An additional skin or outer coating film is not taught present on the device.

Chou et al. teach an extruded implant that includes an outer skin (film). Such coatings are generally known to allow for added control of the release kinetics of the contained active. In particular, the outer layer of Chou et al. is taught to minimize burst release by acting as an additional barrier between the drug/polymer matrix and the aqueous outer environment (see paragraph 35). The outer layer of Chou et al. also gives a release profile with at least a part that is linear (see paragraph 65).

Jain et al. teach that the proteins exhibit a burst release when contained in a PLGA matrix (see figures 2 and 4).

In light of these additional teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PLGA used in the drug core of the device taught by Maquin et al. in an outer skin as taught by Chou et al. to give additional control of the device release kinetics and reduce any burst that occurs. Therefore claims 22-25 are obvious over Maquin et al. in view of Chou et al. and Jain et al.

Response to Arguments and Declaration

Applicants' arguments, filed October 15, 2009, have been fully considered but they are not deemed to be persuasive in light of the new grounds of rejection under 35 USC 103(a). Arguments regarding prior art relied upon in the new grounds of rejection are addressed below..

Regarding prior art cited in rejections under 35 USC 103(a):

Chou et al. – Applicants argue that the profiles of figure 2 based on a PCL core and figure 3 based ion a PLGA are not similar. These profiles are similar in that both show an initial burst that is then followed by a near constant rate of release of drug. Therefore employing either polymer as the core polymer would have been obvious based upon these data and the fact that Chou et al. explicitly teach that either polymer can be selected for this role (see claim 13). Applicants then point to the teachings of Chou et al. that EVA largely retarded the release of FA as compared to PLGA when they are used as coating of FU containing polymer cores as a teaching to one of

ordinary skill that EVA should be considered as a coating polymer. The examiner does not dispute that Chou et al. also envision EVA as a possible coating polymer; however, this does not negate that teachings of PLGA in this role. In addition applicants present an argument based on the faulty conclusion that the examiner believed that the higher the reduction of the initial release the longer the drug release. Such a conclusion was not made in the previous Office action since a particular duration of drug release was not a claimed property. Applicants go on to argue that the reduction in initial burst and "far longer" release obtained by the instant invention is an unexpected result. The reduction in the initial burst is by no means an unexpected result since Chou et al. demonstrate the same phenomenon with the same technique (e.g. presence of PLGA coating see figure 3). Since no side-by-side comparison has been made relative to the closest prior art, the "far longer" release asserted by applicants is unsupported by data. PLGA is explicitly contemplated as a drug core polymer, as well as a coating polymer in Chou et al. Further, Chou et al. explicitly teach drug loading below 55%. Therefore Chou et al. does not teach away from the instant invention and, when combined with Wang et al., make obvious the instant invention as claimed. Applicants continue with the arguments against Chou et al. citing unexpected technical effects, but provide no indication that Chou et al. does not also have these technical effects or that these effects were truly unexpected based on the prior art.

Maquin et al. in view of Chou et al. – Applicants argue that one of ordinary skill would not have looked to Maquin et al. to achieve a reduced initial burst and prolonged linear release profile. "The reason or motivation to modify the reference may often

suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). (see MPEP 2144 IV). In addition, since Jain et al. already acknowledge the burst release obtained from proteins in PLGA matrices and Chou et al. present a means of improving on such devices such that the burst is reduced and a linear profile produced, it would have been obvious to combine these teachings with Maquin et al. as a known technique to improve a similar device in the same way.

Regarding nonstatutory obviousness-type double patenting rejection:

Applicants assert that no feature of the amended claim 22 overlaps with that of claim 1 in US Patent No. 6,620,422. The patent recites a composition with 1 to 60 μm peptide particles dispersed in a PLGA matrix. These features do overlap with those instantly claimed. When coupled with the teachings of Chou et al. and Jain et al. as recited in the rejection, claims 1-3 and 9 make obvious to invention of instant claims 22-24.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615